WORKING WITH LOCAL IRBS IN INTERNATIONAL RESEARCH

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Overview

- Regulatory requirements for U.S. IRBs
- Issues when applying US regulations abroad
- Student research
- Other issues

US Regulatory Requirements

What does your FWA say?

- **If a U.S. institution:**
  - **Ethical standards – Belmont**
  - **Procedural standards = Common Rule**
- **Foreign (non-U.S.) institution:**
  - **CIOMS, Indian, Canadian, Helsinki, "other"**
- **Applicability (HHS? All research?)**

An important clarification before you rely on a foreign IRB

July 7, 2006 Notice on Interpretation of Assurance Requirements

"Some regulated institutions may have been confused by the fact that several … procedural standards are listed on the FWA form for … non-U.S. institutions…"

Interpretation of Assurance Requirements

"…and interpreted this to mean that non-U.S. institutions have a choice of whether or not the requirements of 45 CFR part 46 must be met for HHS conducted or -supported research conducted at their institutions."

"Such an interpretation would be erroneous."

Interpretation of Assurance Requirements

"For HHS-conducted or -supported research, all institutions holding an OHRP approved FWA and engaged in such research must comply with the requirements of 45 CFR part 46. That *compliance is required regardless of whether the institution marked … other procedural standards on the FWA form for international institutions* as a standard to which the institution committed itself to comply."

What do the US regulations say?

45 CFR 45.107(a)

In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.

IRB Membership
45 CFR 46.107(a)

- If an IRB regularly reviews research that involves a vulnerable category of subjects, such as …. consideration shall be given to the ***inclusion*** of one or more ***individuals who are knowledgeable about and experienced in working with these subjects*.**

45 CFR 45.107(f)

An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB.

Bottom line – you need appropriate expertise.

45 CFR 45.111(a)(3)

(3) Selection of subjects is equitable…. IRB … ***should be particularly cognizant of the special problems of research involving vulnerable populations***, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

How will you do that?

Strategies for Success

Meeting Regulatory Requirements

- ID a consultant from / with relevant background and experience
- *Establish dialogue with local IRB*
- Consult with OHRP International Activities staff
- Document findings

Meeting Regulatory Requirements

- Create a supplement to your IRB application
  - Design the questions to address issues
- Require PI attendance at IRB meetings
- Require more rigorous/frequent monitoring

Other Resources

- NBAC report on international research
- CIOMS and other international guidelines
- PRIM&R Membership
- IRB Forum (www.irbforum.org)
- Fogarty International Center

Identifying and Addressing Challenges when Exporting US Regulations

Challenge: Settings

Addressing the Challenge

- Know the environment where the research will be conducted
  - Rural or urban
  - Type of site (clinic, hospital)
  - Site research experience
  - Relevant standards of care

Challenge: Informed Consent

- The Application of Western Informed Consent Standards Abroad
  - Different beliefs about autonomy
  - Role of elders / community leaders
  - Translation issues
  - Documentation issues

Addressing the Challenge

- Ensure the IRB's understanding of the informed consent process for the study
  - Who will obtain consent?
  - Where will the consent process take place?
  - How long will it take?
  - How are translations handled?
- Obtain credible information about documentation practices

Challenge: Research with minors

- Research with Minors
  - Parental permission requirements
  - Local definitions of minor
  - Research on sensitive topics
  - Research with OVC

Addressing the Challenge

- Determine the local age of adulthood (you may get conflicting answers – document source)
- Identify local parental permission requirements
- Understand who can give consent for orphans and other children in unique circumstances

Challenge: Local Laws

- Knowledge of local research settings
  - Absence of laws/regulations
  - Local law versus standard practices
  - Varying quality/existence of local IRBs
  - Multi-national research = multiple local norms

Addressing the Challenges

- ID a consultant from / with experience
- Establish dialogue with local IRB
- Consult with OHRP International Activities staff
- Document findings

Student Research

Considerations in international student research

- **Faculty mentor**
- **Local collaborator?**
- **Local review requirements**
- **Security / health issues**
- **Visa issues (tourist? student?)**

Other issues

Additional considerations

- **Insurance requirements**
  - **Institutional liability; trial participants**
- **MOUs**
- **Security / health issues for travelers**
- **Export restrictions of data / specimens**

Document your findings!!!

Questions & Comments